

**REMARKS**

Claims 1-6 and 8 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,952,370 to Cummings, *et al.* ("Cummings").

Claims 1-8 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,512,951 to Koubek ("Koubek").

Claim 7 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Cummings in view of U.S. Patent No. 5,525,295 to Pflug, *et al.* ("Pflug").

In addition, double-patenting rejections have been entered against the pending claims in view of the claims in co-pending applications Ser. Nos. 09/941,925, 10/363,546 and 10/759,071.

**1. The § 112 Issues Will Be Addressed By The Amendments.**

The Applicants are requesting entry of an amendment to claim 1 to clarify that the recited rapid expansion occurs abruptly, *i.e.*, "wherein expanding and condensing the vapor compound takes place within several tenths of a second up to several seconds." No new matter is added by these amendments, as typical time frames for such expansion are discussed in the original specification. *See, e.g.*, Specification ¶ [0003] ("is abruptly deposited in a time spanning a few tenths of a second to a maximum of a few seconds").

Entry of an amendment to claim 3 is also requested to recite that the pre-heated "warm air" is pre-heated to a temperature "set to maintain a homogeneous temperature condition in the sterilization chamber," a desired end condition described in the Specification at, *e.g.*, ¶ [0014]. The Applicants submit that one of ordinary skill in the art can readily understand and implement

control of the pre-heating air temperature to heat the surfaces entering the chamber to achieve the desired homogeneous temperature condition.

Finally, entry of an amendment to claim 8 to address the objection to the use of the term “hot” is respectfully requested (the Applicants note that the objected-to “rapid” term was deleted in the February 22, 2005 amendments). As noted in Specification P [0033], the hot air is applied to further increase the process effectiveness. Thus, the Applicants are proposing amendment to recite that “the objects are subject to a hot air current after the condensate layer has been sucked out [wherein], a temperature of said hot air being set above a temperature of the objects following removal of the condensate layer.” As with claim 3, it is respectfully submitted that one of ordinary skill in the art would readily understand and be able to set the hot air temperature to exceed the temperature of the objects after the condensate layer has been removed.

Entry of these amendments and withdrawal of the pending § 112, second paragraph rejection is respectfully requested.

**2. Claim 1 Is Distinguishable Over The Cited References.**

As noted in the Applicants’ February 22, 2005 Amendment, the claimed invention provides an apparatus and method in which an aqueous hydrogen peroxide solution is abruptly expanded, such that resulting over-saturated vapor, nearly instantaneous forms a condensate film on the surfaces of the objects to be sterilized, and the resulting release of the heat of evaporation heats the hydrogen peroxide, greatly increasing its disassociation and thus its effectiveness as a sterilization agent.

In contrast, Cummings teaches a relatively long sterilization process, in

which hydrogen peroxide is essentially continuously injected into a chamber to contact objects whose surfaces must be initially cooler than the incoming vapor. A significant amount of time is required for the gradual condensation of the vapor onto the cooler objects, during which additional vapor is also continuously injected into the sterilization chamber (necessary in order to maintain a sufficient concentration of hydrogen peroxide on the object surface as the hydrogen peroxide both disassociates and evaporates in the presence of a water-removing vacuum). The Cummings approach is further complicated by the need to carefully maintain the water-removing vacuum between the evaporation point of water and the evaporation point of hydrogen peroxide, and to continuously cooled the objects' surface to ensure surface temperatures do not rise. Cummings at 2:41-64 ("The vapor phase hydrogen peroxide is continued to be introduced into the chamber until the surfaces are sterile while preserving the temperature ranges of both the first [10°C] and second [20°C] portions of the surfaces."); 3:47-54 (vacuum established to preferentially extract water); 3:55-60 ("injections of vapor phase hydrogen peroxide continue, thereby establishing a flow through the system"); 5:57-7:7 (full process description). Cummings thus disadvantageously requires considerable time to achieve the desired sterilization. *See, e.g.*, Cummings at 6:14-16 (initial vapor introduction "for approximately one minute"); 6:44-48 (subsequent additional hydrogen peroxide injections over 4 to 32 minutes).

Because Cummings does not teach or suggest claim 1's abrupt vapor expansion in order to quickly apply a condensate film to an object (*i.e.*, on the order of minutes, not a "within several tenths of a second up to several seconds"),

this reference fails to teach or suggest all the featured of the present claims for which it is cited.<sup>1</sup>

The Koubek reference similarly teaches a slow sterilization process, not the highly efficient rapid process in which “expanding and condensing the vapor compound takes place within several tenths of a second to up to a few seconds.”

As previously noted, Koubek discloses exposure of an object in an open tray to a hydrogen peroxide vapor, by a slow “dip” process, with each “dip” being caused by continued condensation and application of a liquid sterilant to evacuated surfaces. Koubek at 2:40-56; Fig. 1. As disclosed in Koubek, this is not a rapid process, taking from minutes to hours to complete. Koubek at 4:64-65. Because Koubek does not disclose or suggest the present invention’s abrupt phase-changing approach to sterilization, claims 1-8 are patentable over this references under § 102(b).

### **3. Withdrawal Of The Double Patenting Rejections Is Requested.**

The Applicants respectfully traverse the pending provisional double patenting rejections of the claims over claims 1-20 of co-pending Application Ser. No. 09/941,925, claims 1-18 of co-pending Application Ser. No. 10/759,071 and claims 1-16 of co-pending Application Ser. No. 10/363,546, on the grounds that these claims are patentably distinct from the present invention.

Application Ser. No. 10/363,546: The present process claims recite steps to achieve condensation of a sterilizing medium by abruptly expanding the medium,

---

<sup>1</sup> As to claim 7, the deficiencies of Cummings are not cured by the Pflug reference, which teaches noting with regard to the present abrupt expansion and condensation process.

*i.e.*, rapidly *decreasing vapor temperature* until the vapor is below its condensation point. The process claims of the '546 Application recite essentially the opposite process from a thermodynamic standpoint – *increasing vapor pressure* until the vapor is below its condensation point. Thus, the pending process claims and the process claims of the '546 Application are patentably distinct over one another.

Application Ser. No. 10/759,071: There is nothing in the '071 Application which provides any suggestion of the features of the present claims, nor would it have been obvious to obtain the invention recited in the present claims starting from the '071 Application disclosure.

The '071 Application claims improve on the abrupt vapor expansion process by the use of a low-heat conducting, non-adsorptive material for the structure of a sterilization chamber, thereby minimizing condensation of the vapor on the walls when the vapor abruptly expands. In contrast, where the '071 Application approach provides a passive approach to avoiding wall condensation by preventing excessive wall *cooling* of the vapor, the present Application is directed to *heating* of “at least one of the surfaces of the objects to be sterilized and the sterilization chamber” in order to *enhance evaporation* of the sterilizing material from the objects as well as the walls. *See, e.g.*, Present Specification ¶ [0007]-[0010]. In other words, where the '071 Application prevents heat *loss* (maximizing the amount of vapor available to *condense* on the target objects), the present Application teaches *adding* heat to the objects to enhance *evaporation*, not *condensation*. The Applications thus teach away from one another.

Because the present claims are drawn to an improvement of the abrupt vapor expansion sterilization process which is not suggested by, or otherwise obvious in view of, the '071 Application, the Applicants respectfully submit that a *prima facie* showing of obviousness of the present claims over the '071 claims has not been made. Reconsideration and withdrawal of the pending provisional double-patenting rejection based on the '071 Application is respectfully requested.

Application Ser. No. 09/941,925: As noted above, the invention recited in the pending claims relies on essentially adiabatic expansion of the hydrogen peroxide vapor to generate an over-saturated mixture, with enhanced sterilization of a target surface by the energy of evaporation causing the heating of the condensed mixture to increase hydrogen peroxide disassociation, along with heating of "at least one of the surfaces of the objects to be sterilized and the sterilization chamber" to enhance evaporation of the sterilizing material from the objects and/or the chamber walls. *See, e.g.*, Present Specification ¶[0007]-[0010]. In other words, the present sterilization process requires preheating to ensure the sterilization process is completely effective by removal of residual dipole-bonded sterilant as the condensing/evaporation process is driven to completion.

The '925 Application claims are directed to a process which does not rely on an external heat source to enhance evaporation or to increase hydrogen peroxide disassociation. As with the '071 Application, in the absence of any teaching or suggestion of the present claims' improvement on the abrupt expansion/condensation sterilization process, the Applicants respectfully submit that a *prima facie* showing of obviousness of the present claims over the '925

claims has not been made. Reconsideration and withdrawal of the pending provisional double-patenting rejection based on the '925 Application is respectfully requested.

**CONCLUSION**

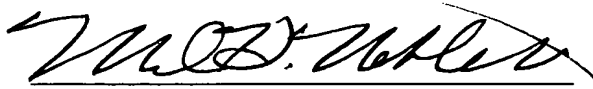
In view of the foregoing, the Applicants respectfully submit that on entry of the requested amendments, claims 1-8 would be in condition for allowance. Early and favorable consideration and issuance of a Notice of Allowance for claims 1-8 is respectfully requested.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket #029082.53212US).

October 6, 2005

Respectfully submitted,



Donald D. Evenson, Reg. No. 26,160  
Mark H. Neblett, Reg. No. 42,028

CROWELL & MORING, LLP  
P.O. Box 14300  
Washington, DC 20044-4300  
Telephone No.: (202) 624-2500  
Facsimile No.: (202) 628-8844